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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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02/13/2004

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EXAMINER

SCHWARTZ, JORDAN MARC

ART UNIT

PAPER NUMBER

2873

DATE MAILED: 02/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/745,511	Applicant(s) CLARK ET AL.	
	Examiner Jordan M. Schwartz	Art Unit 2873	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 8, 10, 11 and 14-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 8, 10, 11 and 14-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/14/03</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

Claim 36 is objected to because of the following informalities: the claim needs to end in a period. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 8, 10, 15, 17-18, 21-22 and 25-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Rawlings patent no. 5,120,121 (hereinafter referred to as "Rawlings'121).

Rawlings'121 reads on these claims by disclosing the limitations therein including the following: a contact lens (abstract); comprising one surface having a "base layer" (Figure 4, column 9, line 48, the tint mask underlay or overlay being considered as the "base layer"); the base layer having a clear central zone (Figure 4) and a translucent color zone (Figure 4, column 16, line 59 to column 17, line 2 and column 17, line 9 i.e. any dot within the pattern being considered as a "translucent color zone"). Rawlings'121 further discloses one or more additional color layers (Figures 3 and 5, column 15, line 47, column 16, lines 36-62 with the iris patterning portion of Figure 3 considered as the "additional color layer"); the additional color layer as either a second translucent layer or an opaque layer (column 8, line 16); the additional color layer has a clear central zone

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and a color layer (Figure 3). So, the mask layer can be considered as the “base layer” which is disclosed as having a clear central zone and a translucent color zone and the colored pattern layer can be considered as the “one or more additional color layer” and it is disclosed as being either translucent or opaque and having a clear central zone and a color zone. Furthermore, since applicant is not disclosing any difference in structure between the “base layer” and the “one or more additional color layers” then the iris patterning portion of Figure 3 can be considered as either the “base layer” or the “additional color layer” and the tint mask underlay of Figure 4 can be considered as either the “base layer” or the “additional color layer”.

In reference to the claimed “color throughout the translucent color zone” since applicant has not claimed a location, size or amount of coverage for the translucent color zone, then any of the dots within the dot pattern of Figure 4 of Rawlings et al or any of the striations of Figure 3 of Rawlings et al can be considered as a “translucent color zone” and each of the individual dots or striation within the pattern will have color throughout them and therefore will comprise color “throughout the translucent color zone”.

Rawlings’121 further discloses the color zones covering greater than 85 percent of the area of the iris (figure 5, column 6, line 67 to column 7, line 12); greater than “about 90 percent” (column 6, line 30, column 7, line 5). In reference to claim 4, since Rawlings’121 discloses that the colored portions of Figures 1-2 can have a central clear and a translucent color zone (column 8, line 16) then the Figure 2 layer can be considered as the “base layer” and the mask layer can be considered as the “additional

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color layer” and Rawlings’121 therefore discloses the layers coverage within the claimed percentages (Figures 2 and 4, column 6, line 67 to column 7, line 12).

Rawlings’121 further discloses the base layer comprising shapes of striae (Figure 4) or lines (Figures 1-2 if the colored pattern layer and not the mask layer is considered as the “base layer”); and that multiple layers can be applied to the same surface (column 8, lines 50-59). In reference to claim 15, Rawlings’121 further discloses a clear pre-polymer layer (column 12, lines 5-28) and regardless, since the base layers are being applied to a contact lens surface, the contact lens surface will inherently comprise a pre-polymer layer. Rawlings’121 further discloses that the method can comprise depositing onto a molding surface the layers (column 7, line 46 to column 8, line 34 and column 11, line 45 to column 15, line 36) and the deposition by pad printing (column 11, line 51-58).

In reference to the claimed translucent color zone “of a uniform color”, Rawlings discloses the masking color formed of a single color (column 17, line 9) and this single color will inherently be “uniform” this being reasonably based upon Rawlings disclosing the colorant of a conventional dye which are known in the art to include uniform colors (column 12, line 15) as well as upon Rawlings not disclosing that the colorant of the mask varies in color. Furthermore, since applicant is claiming “a translucent color zone of a uniform color” and is not claiming any particulars of the zone i.e. location, size etc then any single striae or any portion of any of the striations of Figure 3 or any of the dots within the dot pattern of Figure 4 can be considered as a “translucent color zone” and the color within this “zone” will be uniform for the reasons stated above.

Claims 1, 11, 14-15, 17-25, 33-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Knapp patent no. 4,720,188 (hereinafter referred to as "Knapp'188).

Knapp'188 reads on these claims by disclosing the limitations therein including the following: a contact lens (abstract); comprising one surface having a "base layer" (column 2, line 54 to column 3, line 2 i.e. the layer having the pattern of dots); the base layer having a clear central zone (column 3, line 26 in that the dot pattern is deposited on the iris section and therefore the central pupil section is a clear central zone) and a translucent color zone (column 2, line 67 and column 3, line 26 in that the dot pattern is deposited on the iris section and is disclosed as translucent). Knapp'188 further discloses one or more additional color layers (column 4, line 5); the additional color layer as either a second translucent layer or an opaque layer (column 2, line 67); the additional color layer has a clear central zone and a color layer (column 3, line 26 in that the dot pattern is deposited on the iris section and therefore the central pupil section is a clear central zone and column 2, line 67 and column 3, line 26 in that the dot pattern is deposited on the iris section and is disclosed as translucent). So, the first printed pattern can be considered as the "base layer" which is disclosed as having a clear central zone and a translucent color zone and the colored pattern layer can be considered as the repeat of the pattern and it is disclosed as being either translucent or opaque and will likewise have a clear central zone and a color zone. Knapp'188 further discloses the layers having a radially gradient density (column 3, lines 9-14); the layers comprising shapes of circles (Figure 2). In reference to claim 15, since the patterns i.e.

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layers are being applied to a contact lens surface, the contact lens surface will inherently comprise a pre-polymer layer.

In reference to the claimed "color throughout the translucent color zone" since applicant has not claimed a location, size or amount of coverage for the translucent color zone, then any of the dots within the dot pattern of Figure 4 of Knapp can be considered as a "translucent color zone" and each of the individual dots within the pattern will have color throughout them and therefore will comprise color "throughout the translucent color zone".

In reference to the claimed translucent color zone "of a uniform color", Knapp'188 discloses the masking color formed of a single color (column 2, line 67 i.e. "pigment") and this single color will inherently be "uniform" this being reasonably based upon it being well known in the art of colored lenses that conventional dyes and pigments include those of uniform colors as well as upon Knapp'188 not disclosing that the pigment varies in color. Furthermore, since applicant is claiming "a translucent color zone of a uniform color" and is not claiming any particulars of the zone i.e. location, size etc then any single colored dot or pattern can be considered as a "translucent color zone" and the color within this "zone" will be uniform for the reasons stated above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rawlings'121 or Knapp'188.

Rawlings'121 and Knapp'188 disclose as is set forth above but do not specifically disclose the lens comprising one of acquafilcon, etafilcon, genfilcon or lenefilcon (as this claim is understood). However, the examiner takes Judicial Notice that it is well known in the art of contact lenses for such lenses to comprise one or more of the above materials. Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to have the contact lens of Rawlings'121 or Knapp'188 as comprising one of acquafilcon, etafilcon, genfilcon or lenefilcon since such materials are well known in the art of contact lenses as a material used for making contact lenses.

Claims 11, 14, 19-20 and 23-24, 35-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rawlings'121 in view of Knapp'188.

In reference to these claims, Rawlings'121 discloses as is set forth above but discloses the color zones of uniform color and not of radially gradient colors as claimed. Knapp'188 teaches that in colored contact lenses comprising central clear zones and colored zones to simulate the iris that it is desirable to use a radially gradient pattern for the purpose of providing a more natural looking iris (column 3, lines 9-15). Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to have the color zones of Rawlings'121 of radially gradient colors since Knapp'188 teaches that in colored contact lenses comprising central clear zones and

colored zones to simulate the iris that it is desirable to use a radially gradient pattern for the purpose of providing a more natural looking iris.

Response to Arguments

Applicant's arguments filed November 14, 2003 have been fully considered but they are not persuasive. Specifically, applicant argues that neither Rawlings et al or Knapp disclose the translucent color zone having color throughout. However, applicant is broadly claiming "a translucent color zone" and, as stated in the rejection above, is not claiming any particulars about the location, size or amount of coverage for the translucent color zone. Therefore, as stated in the rejections above, any of the dots within the dot patterns or any of the striations within the striation patterns can be considered as the "translucent color zone" and each of the individual dots or striations within the pattern will have color throughout them and therefore will comprise color "throughout the translucent color zone". Furthermore, if applicant's intended meaning was that the translucent color zone covers the entire iris of the wearer and comprises color throughout the translucent color zone (which was not the assumed meaning since this was not claimed by applicant) then apparently this limitation would lack support within the specification and Figures. Apparently, all of applicant's Figures disclose non-translucent areas within the "translucent color zone". For example, Figure 5 discloses white wavy lines within the patterning i.e. the color zone does not comprise color throughout. Figure 8 is a Figure disclosing multiple layers on the lens and therefore does not disclose just the translucent color zone with color throughout. Other embodiments of applicant state that the color zone is formed by patterning such as the

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last line of page 8 of the specification, which states that the translucent color zone comprises a plurality of clear, colorless feather like shapes. Therefore, the colorless portions of the pattern as well as the spaces between the patterning will not have color and therefore the entire "translucent zone" (if the intended meaning is the entire iris portion) will not have "color throughout".

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jordan M. Schwartz whose telephone number is (703) 308-1286. The examiner can normally be reached on Monday to Friday (8:00-5:30), alternate Fridays off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Georgia Y. Epps can be reached at (703) 308-4883. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7722 for regular communications and (703) 308-7722 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0956.

A handwritten signature in black ink, appearing to read 'J. Schwartz', with a large, stylized loop at the end.

Jordan M. Schwartz
Primary Examiner
Art Unit 2873
February 9, 2004